

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS**

REBECCA FELDMAN,

Plaintiff,

V.

**STRYKER CORPORATION; HOWMEDICA
OSTEONICS CORPORATION d/b/a
STRYKER ORTHOPAEDICS; AAP
BIOMATERIALS GMBH; AAP
IMPLANTATE AG; and AAP IMPLANTS,
INC.,**

Defendants.

CASE NO. 3:18-cv-01416

**HOWMEDICA OSTEONICS CORPORATION'S ORIGINAL
ANSWER TO PLAINTIFF'S COMPLAINT AND AFFIRMATIVE DEFENSES**

Defendant Howmedica Osteonics Corporation ("HOC"), by and through its undersigned counsel, hereby submits the following Answer and Affirmative Defenses to Plaintiff's Original Complaint. HOC denies each and every allegation, statement, matter, and thing contained in Plaintiff's Complaint, except as is hereinafter expressly admitted or alleged.

PARTIES, JURISDICTION, AND VENUE

1. HOC is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 1 of Plaintiff's Complaint, and therefore denies such allegations.

2. The allegations contained in Paragraph 2 of Plaintiff's Complaint are not directed at HOC and therefore no response is required. To the extent a response is required, HOC states that it is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 2 of Plaintiff's Complaint, and therefore denies such allegations.

3. HOC admits that it is New Jersey corporation and that its principal place of business is located at 325 Corporate Boulevard, Mahwah, New Jersey 07430. HOC further admits that it is a wholly owned subsidiary of Stryker Corporation. By filing this Answer, HOC further states that it does not contest personal jurisdiction in this case based on any potential error in service of process as to HOC.

4. The allegations contained in Paragraph 4 of Plaintiff's Complaint are not directed at HOC and therefore no response is required. To the extent a response is required, HOC states that it is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 4 of Plaintiff's Complaint, and therefore denies such allegations.

5. The allegations contained in Paragraph 5 of Plaintiff's Complaint are not directed at HOC and therefore no response is required. To the extent a response is required, HOC states that it is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 5 of Plaintiff's Complaint, and therefore denies such allegations.

6. The allegations contained in Paragraph 6 of Plaintiff's Complaint are not directed at HOC and therefore no response is required. To the extent a response is required, HOC states that it is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 6 of Plaintiff's Complaint, and therefore denies such allegations.

7. The allegations in Paragraph 7 of Plaintiff's Complaint are legal conclusions to which no response is required. To the extent a response is required, HOC denies the allegations in Paragraph 7 of Plaintiff's Complaint.

8. HOC admits that it distributes, sells, and markets Simplex HV bone cement in the United States. HOC denies the remaining allegations in Paragraph 8 of Plaintiff's Complaint.

9. The allegations in Paragraph 9 of Plaintiff's Complaint are legal conclusions to which no response is required. To the extent a response is required, HOC admits that this Court has subject matter jurisdiction over this action based on the information currently available to HOC.

10. The allegations in Paragraph 10 of Plaintiff's Complaint are legal conclusions to which no response is required.

BACKGROUND

11. Paragraph 11 of Plaintiff's Complaint alleges complex, medical information that is not reasonably available to HOC's counsel at this time and is best addressed by expert medical testimony. To the extent a response is currently required, HOC denies the allegations in Paragraph 11 of Plaintiff's Complaint.

12. Paragraph 12 of Plaintiff's Complaint alleges complex, medical information that is not reasonably available to HOC's counsel at this time and is best addressed by expert medical testimony. To the extent a response is currently required, HOC denies the allegations in Paragraph 12 of Plaintiff's Complaint.

13. Paragraph 13 of Plaintiff's Complaint alleges complex, medical information that is not reasonably available to HOC's counsel at this time and is best addressed by expert medical testimony. To the extent a response is currently required, HOC denies the allegations in Paragraph 13 of Plaintiff's Complaint.

14. Paragraph 14 of Plaintiff's Complaint alleges complex, medical information that is not reasonably available to HOC's counsel at this time and is best addressed by expert medical testimony. To the extent a response is currently required, HOC denies the allegations in Paragraph 14 of Plaintiff's Complaint.

15. Paragraph 15 of Plaintiff's Complaint alleges complex, medical information that is not reasonably available to HOC's counsel at this time and is best addressed by expert medical testimony. To the extent a response is currently required, HOC denies the allegations in Paragraph 15 of Plaintiff's Complaint.

16. HOC admits that it markets and sells Simplex HV bone cement in the United States.

17. HOC admits that Simplex P is not a high viscosity bone cement. HOC further states that the allegations in Paragraph 17 of Plaintiff's Complaint purport to selectively paraphrase unknown documents, and HOC denies that the documents are paraphrased in context or in their entirety and denies Plaintiff's characterization of the documents. HOC states that the documents paraphrased in Paragraph 17 of Plaintiff's Complaint speak for themselves, and HOC denies the allegations in Paragraph 17 of Plaintiff's Complaint to the extent they are inconsistent with the paraphrased documents.

18. HOC admits that Simplex P is not a high viscosity bone cement. HOC further states that the allegations in Paragraph 18 of Plaintiff's Complaint purport to selectively paraphrase unknown documents, and HOC denies that the documents are paraphrased in context or in their entirety and denies Plaintiff's characterization of the documents. HOC states that the documents paraphrased in Paragraph 18 of Plaintiff's Complaint speak for themselves, and HOC denies the allegations in Paragraph 18 of Plaintiff's Complaint to the extent they are inconsistent with the paraphrased documents.

19. The allegations in Paragraph 19 of Plaintiff's Complaint purport to selectively paraphrase unknown documents, and HOC denies that the documents are paraphrased in context or in their entirety and denies Plaintiff's characterization of the documents. HOC states that the documents paraphrased in Paragraph 19 of Plaintiff's Complaint speak for themselves, and HOC

denies the allegations in Paragraph 19 of Plaintiff's Complaint to the extent they are inconsistent with the paraphrased documents.

20. The allegations in Paragraph 20 of Plaintiff's Complaint purport to selectively paraphrase unknown documents, and HOC denies that the documents are paraphrased in context or in their entirety and denies Plaintiff's characterization of the documents. HOC states that the documents paraphrased in Paragraph 20 of Plaintiff's Complaint speak for themselves, and HOC denies the allegations in Paragraph 20 of Plaintiff's Complaint to the extent they are inconsistent with the paraphrased documents.

21. HOC admits that it markets and sells Simplex HV bone cement in the United States. HOC further states that the allegations in Paragraph 21 of Plaintiff's Complaint purport to selectively paraphrase unknown documents, and HOC denies that the documents are paraphrased in context or in their entirety and denies Plaintiff's characterization of the documents. HOC states that the documents paraphrased in Paragraph 21 of Plaintiff's Complaint speak for themselves, and HOC denies the allegations in Paragraph 21 of Plaintiff's Complaint to the extent they are inconsistent with the paraphrased documents. HOC denies any remaining allegations in Paragraph 21 of Plaintiff's Complaint.

22. HOC admits that Simplex HV is a high viscosity bone cement. HOC further denies the remaining allegations in Paragraph 22 of Plaintiff's Complaint.

23. HOC admits that Simplex HV was cleared to be marketed in the United States by the Food and Drug Administration (FDA) under the 510(k) process. HOC further states that the 510(k) process is an FDA-approved process for clearing medical devices in the United States. HOC further states that the regulatory documents referenced in Paragraph 23 of Plaintiff's Complaint speak for themselves, and HOC denies the allegations in Paragraph 23 of Plaintiff's

Complaint to the extent they are inconsistent with the paraphrased documents. HOC further denies any remaining allegations in Paragraph 23 of Plaintiff's Complaint.

24. HOC admits that Simplex HV was cleared to be marketed in the United States by the Food and Drug Administration under the 510(k) process. HOC further states that the regulatory documents referenced in Paragraph 24 of Plaintiff's Complaint speak for themselves, and HOC denies the allegations in Paragraph 24 of Plaintiff's Complaint to the extent they are inconsistent with the paraphrased documents. HOC further states that the allegations in Paragraph 24 of Plaintiff's Complaint purport to selectively paraphrase unknown documents, and HOC denies that the documents are paraphrased in context or in their entirety and denies Plaintiff's characterization of the documents. HOC states that the documents paraphrased in Paragraph 24 of Plaintiff's Complaint speak for themselves, and HOC denies the allegations in Paragraph 24 of Plaintiff's Complaint to the extent they are inconsistent with the paraphrased documents. HOC denies any remaining allegations in Paragraph 24 of Plaintiff's Complaint.

25. HOC states that the allegations in Paragraph 25 of Plaintiff's Complaint purport to selectively paraphrase unknown documents, and HOC denies that the documents are paraphrased in context or in their entirety and denies Plaintiff's characterization of the documents. HOC states that the documents paraphrased in Paragraph 25 of Plaintiff's Complaint speak for themselves, and HOC denies the allegations in Paragraph 25 of Plaintiff's Complaint to the extent they are inconsistent with the paraphrased documents. HOC denies any remaining allegations in Paragraph 25 of Plaintiff's Complaint.

26. HOC states that the allegations in Paragraph 26 of Plaintiff's Complaint purport to selectively paraphrase unknown documents, and HOC denies that the documents are paraphrased in context or in their entirety and denies Plaintiff's characterization of the documents. HOC states

that the documents paraphrased in Paragraph 26 of Plaintiff's Complaint speak for themselves, and HOC denies the allegations in Paragraph 26 of Plaintiff's Complaint to the extent they are inconsistent with the paraphrased documents. HOC denies any remaining allegations in Paragraph 26 of Plaintiff's Complaint.

27. HOC states that the allegations in Paragraph 27 of Plaintiff's Complaint purport to selectively paraphrase unknown documents, and HOC denies that the documents are paraphrased in context or in their entirety and denies Plaintiff's characterization of the documents. HOC states that the documents paraphrased in Paragraph 27 of Plaintiff's Complaint speak for themselves, and HOC denies the allegations in Paragraph 27 of Plaintiff's Complaint to the extent they are inconsistent with the paraphrased documents. HOC denies any remaining allegations in Paragraph 27 of Plaintiff's Complaint.

28. HOC denies the allegations in Paragraph 28 of Plaintiff's Complaint.

29. HOC denies the allegations in Paragraph 29 of Plaintiff's Complaint.

30. HOC denies the allegations in Paragraph 30 of Plaintiff's Complaint.

31. HOC denies the allegations in Paragraph 31 of Plaintiff's Complaint.

32. HOC admits that its Simplex HV bone cement is a safe and effective product. HOC further states that the allegations in Paragraph 32 of Plaintiff's Complaint purport to selectively paraphrase unknown documents, and HOC denies that the documents are paraphrased in context or in their entirety and denies Plaintiff's characterization of the documents. HOC states that the documents paraphrased in Paragraph 32 of Plaintiff's Complaint speak for themselves, and HOC denies the allegations in Paragraph 32 of Plaintiff's Complaint to the extent they are inconsistent with the paraphrased documents. HOC denies any remaining allegations in Paragraph 32 of Plaintiff's Complaint.

33. HOC admits that its Simplex HV bone cement is a safe and effective product. HOC further states that the allegations in Paragraph 33 of Plaintiff's Complaint purport to selectively paraphrase unknown documents, and HOC denies that the documents are paraphrased in context or in their entirety and denies Plaintiff's characterization of the documents. HOC states that the documents paraphrased in Paragraph 33 of Plaintiff's Complaint speak for themselves, and HOC denies the allegations in Paragraph 33 of Plaintiff's Complaint to the extent they are inconsistent with the paraphrased documents. HOC denies any remaining allegations in Paragraph 33 of Plaintiff's Complaint.

34. HOC admits that its Simplex HV bone cement is a safe and effective product. HOC further states that the allegations in Paragraph 34 of Plaintiff's Complaint purport to selectively paraphrase unknown documents, and HOC denies that the documents are paraphrased in context or in their entirety and denies Plaintiff's characterization of the documents. HOC states that the documents paraphrased in Paragraph 34 of Plaintiff's Complaint speak for themselves, and HOC denies the allegations in Paragraph 34 of Plaintiff's Complaint to the extent they are inconsistent with the paraphrased documents. HOC denies any remaining allegations in Paragraph 34 of Plaintiff's Complaint.

35. HOC denies the allegations in Paragraph 35 of Plaintiff's Complaint.

CASE SPECIFIC FACTUAL ALLEGATIONS

36. HOC denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 36 of Plaintiff's Complaint and therefore denies the allegations.

37. HOC denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 37 of Plaintiff's Complaint and therefore denies the allegations.

38. HOC denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 38 of Plaintiff's Complaint and therefore denies the allegations. To the extent the allegations in Paragraph 38 of Plaintiff's Complaint allege wrongdoing, liability, or damages attributable to HOC, they are denied.

39. HOC denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 39 of Plaintiff's Complaint and therefore denies the allegations.

40. HOC denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 40 of Plaintiff's Complaint and therefore denies the allegations. To the extent the allegations in Paragraph 40 of Plaintiff's Complaint allege wrongdoing, liability, or damages attributable to HOC, they are denied.

COUNT I: STRICT PRODUCTS LIABILITY – DESIGN DEFECT

41. HOC incorporates by reference its responses to all preceding paragraphs as if fully set forth herein.

42. HOC admits that it marketed, sold, and distributed Simplex HV bone cement in the United States. HOC denies any remaining allegations in Paragraph 42 of Plaintiff's Complaint.

43. HOC denies the allegations in Paragraph 43 of Plaintiff's Complaint.

44. HOC denies the allegations in Paragraph 44 of Plaintiff's Complaint.

45. HOC denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 45 of Plaintiff's Complaint and therefore denies the allegations.

46. HOC denies the allegations in Paragraph 46 of Plaintiff's Complaint.

47. HOC denies the allegations in Paragraph 47 of Plaintiff's Complaint.

48. HOC denies the allegations in Paragraph 48 of Plaintiff's Complaint.

49. HOC denies the allegations in Paragraph 49 of Plaintiff's Complaint.

50. HOC denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 50 of Plaintiff's Complaint and therefore denies the allegations.

51. The allegations contained in Paragraph 51 of Plaintiff's Complaint are legal conclusions and therefore no response is required. To the extent a response is required, HOC denies the allegations in Paragraph 51 of Plaintiff's Complaint. HOC further denies any remaining allegations in Paragraph 51 of Plaintiff's Complaint.

52. HOC denies the allegations in Paragraph 52 of Plaintiff's Complaint.

53. HOC admits that it promoted, marketed, and sold the Simplex HV bone cement in the United States. HOC denies the remaining allegations in Paragraph 53 of Plaintiff's Complaint.

54. HOC denies the allegations in Paragraph 54 of Plaintiff's Complaint.

WHEREFORE, Defendant HOC demands judgment in its favor and against Plaintiff, dismissing Plaintiff's Complaint with prejudice, together with the costs of suit and such other relief as the Court deems equitable and just.

COUNT II: STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT

55. HOC incorporates by reference its responses to all preceding paragraphs as if fully set forth herein.

56. HOC admits that it distributed and sold the Simplex HV bone cement in the United States. HOC denies the remaining allegations in Paragraph 56 of Plaintiff's Complaint.

57. HOC denies the allegations in Paragraph 57 of Plaintiff's Complaint.

58. HOC denies the allegations in Paragraph 58 of Plaintiff's Complaint.

WHEREFORE, Defendant HOC demands judgment in its favor and against Plaintiff, dismissing Plaintiff's Complaint with prejudice, together with the costs of suit and such other relief as the Court deems equitable and just.

COUNT III: STRICT PRODUCTS LIABILITY – FAILURE TO WARN

59. HOC incorporates by reference its responses to all preceding paragraphs as if fully set forth herein.

60. HOC admits that it marketed and sold the Simplex HV bone cement in the United States. HOC denies the remaining allegations in Paragraph 60 of Plaintiff's Complaint.

61. HOC denies the allegations in Paragraph 61 of Plaintiff's Complaint.

62. HOC denies the allegations in Paragraph 62 of Plaintiff's Complaint.

63. HOC denies the allegations in Paragraph 63 of Plaintiff's Complaint.

64. HOC denies the allegations in Paragraph 64 of Plaintiff's Complaint.

65. HOC denies the allegations in Paragraph 65 of Plaintiff's Complaint.

WHEREFORE, Defendant HOC demands judgment in its favor and against Plaintiff, dismissing Plaintiff's Complaint with prejudice, together with the costs of suit and such other relief as the Court deems equitable and just.

COUNT IV: BREACH OF EXPRESS WARRANTY

66. HOC incorporates by reference its responses to all preceding paragraphs as if fully set forth herein.

67. HOC admits that Simplex HV bone cement is a safe and effective product. HOC further states that the allegations contained in Paragraph 67 of Plaintiff's Complaint are legal conclusions and therefore no response is required. To the extent a response is required, HOC denies the allegations in Paragraph 67 of Plaintiff's Complaint. HOC further denies any remaining allegations in Paragraph 67 of Plaintiff's Complaint.

68. HOC admits that Simplex HV bone cement is a safe and effective product. HOC further states that the allegations contained in Paragraph 68 of Plaintiff's Complaint are legal conclusions and therefore no response is required. To the extent a response is required, HOC denies the allegations in Paragraph 68 of Plaintiff's Complaint. HOC further denies any remaining allegations in Paragraph 68 of Plaintiff's Complaint.

69. HOC denies the allegations in Paragraph 69 of Plaintiff's Complaint.

70. HOC denies the allegations in Paragraph 70 of Plaintiff's Complaint.

71. HOC denies the allegations in Paragraph 71 of Plaintiff's Complaint.

WHEREFORE, Defendant HOC demands judgment in its favor and against Plaintiff, dismissing Plaintiff's Complaint with prejudice, together with the costs of suit and such other relief as the Court deems equitable and just.

COUNT V: BREACH OF IMPLIED WARRANTY

72. HOC incorporates by reference its responses to all preceding paragraphs as if fully set forth herein.

73. HOC admits that it sells Simplex HV bone cement to appropriate healthcare professionals in the United States. HOC denies any remaining allegations in Paragraph 73 of Plaintiff's Complaint.

74. HOC denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 74 of Plaintiff's Complaint and therefore denies the allegations.

75. HOC denies the allegations in Paragraph 75 of Plaintiff's Complaint.

76. HOC denies the allegations in Paragraph 76 of Plaintiff's Complaint.

77. HOC denies the allegations in Paragraph 77 of Plaintiff's Complaint.

78. HOC denies the allegations in Paragraph 78 of Plaintiff's Complaint.

79. HOC denies the allegations in Paragraph 79 of Plaintiff's Complaint.

WHEREFORE, Defendant HOC demands judgment in its favor and against Plaintiff, dismissing Plaintiff's Complaint with prejudice, together with the costs of suit and such other relief as the Court deems equitable and just.

COUNT VI: NEGLIGENCE

80. HOC incorporates by reference its responses to all preceding paragraphs as if fully set forth herein.

81. The allegations contained in Paragraph 81 of Plaintiff's Complaint are legal conclusions and therefore no response is required. To the extent the allegations in Paragraph 81 of Plaintiff's Complaint allege wrongdoing, liability, or damages attributable to HOC, they are denied.

82. HOC denies the allegations in Paragraph 82 of Plaintiff's Complaint.

83. HOC denies the allegations in Paragraph 83 of Plaintiff's Complaint, as well as each and every subpart thereto.

84. HOC denies the allegations in Paragraph 84 of Plaintiff's Complaint.

85. HOC denies the allegations in Paragraph 85 of Plaintiff's Complaint.

86. HOC denies the allegations in Paragraph 86 of Plaintiff's Complaint.

WHEREFORE, Defendant HOC demands judgment in its favor and against Plaintiff, dismissing Plaintiff's Complaint with prejudice, together with the costs of suit and such other relief as the Court deems equitable and just.

PRAYER FOR RELIEF

The allegations contained in Plaintiff's Prayer for Relief are legal conclusions and therefore no response is required. HOC further states that it denies any allegation in this Section that alleges wrongdoing, liability, or damages attributable to HOC, and it expressly denies that Plaintiff is entitled to any form or relief against HOC.

DEMAND FOR JURY TRIAL

HOC demands a trial by jury on all counts and as to all issues.

DEFENSES

HOC asserts the following separate defenses. By alleging the separate defenses set forth below, HOC is not in any way agreeing or conceding it has the burden of proof or the burden of persuasion on any of these issues.

FIRST DEFENSE

Plaintiff's claims are preempted by the Medical Device Amendments to the Food, Drug & Cosmetic Act of 1938.

SECOND DEFENSE

Plaintiff's claims are barred, in whole or in part, by the applicable statute of limitations, statutes of repose, and/or doctrines of laches.

THIRD DEFENSE

Plaintiff's claims are barred, in whole or in part, because of the doctrines of informed consent, release, and waiver.

FOURTH DEFENSE

Plaintiff's claims are impliedly preempted by the FDA's regulation of this field.

FIFTH DEFENSE

Plaintiff's claims are barred, in whole or in part, because the Complaint fails to state a cause of action upon which relief can be granted under applicable law.

SIXTH DEFENSE

Plaintiff's claims are barred, in whole or in part, by the "learned intermediary" or "informed intermediary" doctrine.

SEVENTH DEFENSE

Plaintiff's injuries or damages alleged, if any, were directly and proximately caused in whole or in part by the acts or omissions of a third person or persons. HOC had no reason to anticipate these acts or omissions and is not liable for the acts and omissions of persons it had no knowledge of and over whom it had no control.

EIGHTH DEFENSE

Plaintiff had full knowledge of, accepted, and/or assumed all risks and possible adverse effects related to the use of the product(s) at issue in this matter. Recovery, therefore, is barred under primary assumption of the risk.

NINTH DEFENSE

At all times mentioned herein, Plaintiff was negligent, careless, and at fault, and conducted herself so as to contribute substantially to her alleged injuries and damages. Said negligence, carelessness, and fault of Plaintiff bars, in whole or in part, the damages that Plaintiff seeks to recover herein.

TENTH DEFENSE

Plaintiff's alleged damages, if any, are barred, in whole or in part, by Plaintiff's failure to mitigate any injuries, losses, or damages she may have sustained.

ELEVENTH DEFENSE

Plaintiff's claims are barred, in whole or in part, because, based on the state of scientific, medical, and technical knowledge at the time the product(s) at issue were marketed, it was reasonably safe for its normal and foreseeable uses at all times, it was not unreasonably dangerous or defective, and its benefits exceeded any associated risks.

TWELFTH DEFENSE

Plaintiff's claims are barred, in whole or in part, because the methods, standards, and techniques utilized in manufacturing, distributing, marketing, and labeling the product(s) at issue and in issuing warnings and instructions with respect to its use, conformed with the generally recognized, reasonably available, and reliable state of knowledge at the time the product(s) at issue was manufactured and distributed.

THIRTEENTH DEFENSE

Plaintiff's claims are barred, in whole or in part, to the extent Plaintiff's claims are based on alleged misrepresentations or omissions made to the FDA, pursuant to *Buckman Co. v. Plaintiff's Legal Comm.*, 531 U.S. 341 (2001).

FOURTEENTH DEFENSE

Should HOC be held liable to Plaintiff, which liability is specifically denied, HOC would be entitled to a set-off for the total of all amounts paid to Plaintiff from all collateral sources.

FIFTEENTH DEFENSE

Plaintiff's damages are barred, in whole or in part, to the extent the Court applies Section 6(c) of the Restatement of Torts (Third).

SIXTEENTH DEFENSE

Plaintiff's claims are barred, either in whole or in part, because HOC made no false, material or knowing misrepresentation to Plaintiff's doctors, nor did HOC conceal or omit any material information from Plaintiff's doctors.

SEVENTEENTH DEFENSE

HOC has engaged in no conduct that would warrant the imposition of treble damages, punitive damages, attorneys' fees and/or costs of suit.

EIGHTEENTH DEFENSE

Plaintiff's claims are barred, in whole or in part, because the user of the product at issue was a sophisticated user of the subject product and was aware of any risks that attended its use.

NINETEENTH DEFENSE

Plaintiff is not entitled to recover from HOC for breach of warranty because Plaintiff failed to give notice of the alleged injury and alleged breach of warranty to HOC within a reasonable time and HOC was prejudiced thereby.

TWENTIETH DEFENSE

Plaintiff is barred from pursuing her claims in this Court because venue is improper.

TWENTY-FIRST DEFENSE

Plaintiff is barred from pursuing her claims in this Court because this court lacks jurisdiction over Defendants with regard to these claims.

TWENTY-SECOND DEFENSE

To the extent that Plaintiff seeks an award of punitive and/or treble damages, the imposition of such damages against HOC would violate HOC's rights under the Due Process clauses in the Fifth and Fourteenth Amendments to the Constitution of the United States, the Excessive Fines clause in the Eighth Amendment to the Constitution of the United States, the Double Jeopardy clause in the Fifth Amendment to the Constitution of the United States, the Equal Protection clause of the Fourteenth Amendment to the Constitution of the United States, and the Sixth Amendment to the Constitution of the United States, in several regards, including but not limited to the following:

- a. Imposition of treble and/or punitive damages by a jury which is inadequately instructed regarding the rationale behind punitive damages, the standards/criteria governing such an award of damages, and/or the limits of such damages;
- b. Imposition of treble and/or punitive damages where applicable law is impermissibly vague, imprecise, or inconsistent;
- c. Imposition of treble and/or punitive damages that employs a burden of proof that is less than clear and convincing evidence;
- d. Imposition of treble and/or punitive damages without bifurcating the trial and trying all treble and/or punitive damages issues separately, only if and after a finding on the merits of the liability of HOC;

e. Imposition of treble and/or punitive damages without any predetermined limit on any such award;

f. Imposition of treble and/or punitive damages which allows multiple punishment for the same alleged act(s) or omission(s); and

g. Imposition of treble and/or punitive damages without consistent appellate standards of review of such an award.

TWENTY-THIRD DEFENSE

HOC expressly preserves, and does not knowingly or intentionally waive, any of the other affirmative defenses set forth under Texas or any applicable state law, any other matter constituting an avoidance or affirmative defense, or any cross-claim or counterclaim, which investigation or discovery may reveal to be applicable.

Dated: August 20, 2018.

Respectfully submitted,

SHOOK, HARDY & BACON L.L.P.

/s/ Gene M. Williams

Gene M. Williams
Texas Bar No. 21535300
Benjamin Walther
Texas Bar No. 24084041
JPMorgan Chase Tower
600 Travis, Suite 3400
Houston, TX 77002
Telephone: (713) 227-8008
Facsimile: (713) 227-9508
Email: gmwilliams@shb.com
Email: bwalther@shb.com

***Attorneys for Defendant Howmedica
Osteonics Corporation***

CERTIFICATE OF SERVICE

I, the undersigned attorney, hereby certify that I served a copy of the foregoing document by electronic mail and/or electronic filing notification to the attorneys/parties listed below this 20th day of August, 2018.

Russell R. Reynolds
Texas Bar No. 24009359
Debra S. Reynolds
Texas Bar No. 34043891
THE LAW OFFICES OF REYNOLDS AND REYNOLDS, PLLC
2591 Dallas Pkwy, Suite 300
Frisco, TX 75034
Telephone: (214) 891-6606
Facsimile: (972) 731-4384
Email: rusty@rrlfirm.com
Email: debra@rrlfirm.com

W. Roger Smith III
Ryan J. Duplechin
BEASLEY, ALLEN, CROW, METHVIN, PORTIS & MILES, P.C.
Post Office Box 4160
Montgomery, AL 36103-4160
Telephone: (334) 269-2343
Facsimile: (334) 954-7555
Email: Roger.Smith@BeasleyAllen.com
Email: Ryan.Duplechin@BeasleyAllen.com

Attorneys for Plaintiff

/s/ Gene M. Williams

Gene M. Williams